PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 125.7 and 135.150(1), the Department of Public Health hereby gives Notice of Intended Action to amend Chapter 155, "Licensure Standards for Substance Abuse and Problem Gambling Treatment Programs," Iowa Administrative Code.

Iowa Code section 136.3(13) allows the State Board of Health to appoint a Substance Abuse and Gambling Treatment Program Committee to approve or deny applications for licensure received from substance abuse programs and gambling treatment programs and to perform other functions delegated to the Committee.

These proposed amendments define a Substance Abuse and Gambling Treatment Program Committee and specify the duties of the Committee. The amendments also change "board" to "committee" throughout the chapter in rules where the Board's duties are assumed by the Committee.

These rules are subject to waiver pursuant to 641—Chapter 178.

Any interested person may make written comments on these amendments on or before April 19, 2011, addressed to Bob Kerksieck, Division of Behavioral Health, Department of Public Health, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319-0075; E-mail rkerksie@idph.state.ia.us.

Also, a public hearing will be held on April 19, 2011, from 11 a.m. to 12 noon, at which time persons may present their views either orally or in writing. At the hearing, the Department will ask those persons present to give their names and addresses for the record and to confine their remarks to the subject of the amendments. This hearing will be held in Room 523 of the Lucas State Office Building in Des Moines.

Any person who plans to attend the public hearing and has special requirements, such as those related to hearing or mobility impairments, should contact the Department to advise of specific needs.

These amendments are intended to implement Iowa Code sections 135.150 and 136.3(13) and Iowa Code chapter 125.

The following amendments are proposed.

ITEM 1. Amend rule **641—155.1(125,135)**, definitions of "Accreditation body," "Deemed status" and "Licensure," as follows:

"Accreditation body" means a national or not-for-profit body or organization recognized by the board committee as meeting the criteria of the board committee for deemed status.

"Deemed status" means that the board committee and division will accept a board committee-approved, outside accreditation body's review, assessment and accreditation of a program, component or service of a program/organization's operations and services. Programs which received deemed status approval are exempt from routine licensure requirements; however, such programs are subject to all other provisions of this chapter.

"Licensure" means the issuance of a license by the department and the board committee which validates the licensee's compliance with treatment program standards and authorizes the licensee to operate a treatment program in the state of Iowa.

ITEM 2. Adopt the following <u>new</u> definition of "Committee" in rule 641—155.1(125,135):

"Committee" means the substance abuse and gambling treatment program committee appointed by the state board of health pursuant to Iowa Code section 136.3(13).

- ITEM 3. Amend rule 641—155.2(125,135) as follows:
- **641—155.2(125,135)** Licensing. A single license will be issued to each qualifying treatment program. A program shall apply for a license to provide substance abuse treatment, problem gambling treatment, or combined substance abuse and problem gambling treatment.
- <u>155.2(1)</u> <u>Categories of services.</u> The license will delineate one or more categories of services the program is authorized to provide. Although a program may have more than one facility, only one license will be issued to the program. The categories of services for which licenses will be issued are:
 - + a. Narcotic detoxification/chemical substitute, antagonist maintenance chemotherapy;
 - 2. b. Assessment and evaluation;
 - 3. c. OWI correctional residential;
 - 4. d. OWI correctional outpatient;
 - 5. e. Correctional residential treatment;
 - 6. f. Correctional outpatient treatment;
 - 7. g. Medically managed intensive inpatient services: Level IV;
 - & h. Residential/inpatient services: Levels III.1, III.3, III.5 and III.7;
 - 9. <u>i.</u> Intensive outpatient/partial hospitalization services: Levels II.1 and II.5; and
 - 10. j. Outpatient extended and continuing care services: Level I.
 - 155.2(2) Licensing body. The committee shall:
- a. Consider and approve or disapprove all applications for a license and all cases involving the renewal, denial, suspension, or revocation of a license;
- <u>b.</u> Advise the department on policies governing the performance of the department in the discharge of any duties imposed on the department by law;
- c. Advise or make recommendations to the board relative to substance abuse and gambling treatment, intervention, education, and prevention programs in this state; and
 - d. Perform other duties as assigned by the board.
 - ITEM 4. Amend subrule 155.3(2) as follows:
- **155.3(2)** Corrective action. Following the issuance of a license, the treatment program may be requested by the board committee to provide a written plan of corrective action and to bring into compliance all areas found in noncompliance during the on-site visit. The corrective action plan shall be placed in the program's permanent file with the division and used as reference during future on-site inspections.
 - ITEM 5. Amend subrule 155.4(4) as follows:
- **155.4(4)** Any person or legal entity having acquired a license and desiring to fundamentally alter the treatment philosophy or transfer to a different premises must notify the board committee 30 days prior to said action in order for the department to review the site change and to determine appropriate action.
 - ITEM 6. Amend rule 641—155.5(125,135), introductory paragraph, as follows:
- 641—155.5(125,135) Application procedures. The department shall provide an application to all applicants for licensure. An on-site visit for licensure of an initial applicant shall occur before the program opens and admits client/patients for services. For initial applicants, if technical assistance has been provided, the on-site visit may be waived at the discretion of the department. The division shall prepare a report with a recommendation for licensure to be presented at a board committee meeting within 60 days from the site visit. Public notice for board committee meetings will be made in accordance with Iowa Code section 21.4. The division shall provide notice to the program ten days prior to the board committee meeting notifying the program director and program board chairperson of the time, place, and date the board committee will review and act upon the application for the program along with the results of the inspection. The division shall provide to all board committee members reports of the on-site program licensure inspection and a final recommendation for each application to be acted upon at the next board committee meeting.

- ITEM 7. Amend paragraph **155.5(1)**"i" as follows:
- *i.* Fiscal management information to include a recent audit or opinion of auditor and <u>program</u> board minutes to reflect approval of budget and insurance program.
 - ITEM 8. Amend subrule 155.7(3) as follows:
- **155.7(3)** *Effective date of license.* The effective date of a license shall begin on the date the board committee reviews the program's written report/application and acts to issue a license.
 - ITEM 9. Amend rule 641—155.8(125,135) as follows:
- **641—155.8(125,135)** Licenses—renewal. Upon approval of an application for licensing by the board committee, a license shall be issued by the department. Licenses shall be renewed pursuant to rule 641—155.5(125,135).
- **155.8(1)** Board Committee meeting preparation. The division shall prepare a report with a final recommendation for licensing to be presented at a board committee meeting within 80 days from the site visit. Public notice of board committee meetings shall be made in accordance with Iowa Code section 21.4.
- a. The division shall send notice to the program by certified mail, return receipt requested, ten days prior to the board committee meeting notifying the program director and program board chairperson of the time, place, and date the board committee will review and act upon the application for the program along with the results of the inspection.
- *b*. The division shall mail to all board committee members the following information on each application to be processed at the next board committee meeting:
 - (1) and (2) No change.
 - 155.8(2) Board Committee meeting format.
 - a. to c. No change.
- d. After all concerned parties are heard, the board committee will make a decision as to whether the applicant should be finally approved or initially denied a license to operate a substance abuse treatment program.
 - ITEM 10. Amend rule 641—155.9(125,135) as follows:
- **641—155.9(125,135)** Corrective action plan. Programs approved for a license for 270 days by the board committee shall submit a corrective action plan to the director no later than 30 days following the board committee meeting. The corrective action plan shall include, but not be limited to:
 - 1. to 3. No change.
- 4. A follow-up on-site visit will be required to review the implemented corrective action with a subsequent report to the board committee.

Programs issued a license for a period of one or two years shall submit a corrective action plan for those standards found to be in noncompliance following a licensure inspection. Technical assistance on a corrective action plan shall not be required for one- or two-year licenses. The corrective action plan shall be submitted within 30 days of receipt of the licensure inspection report.

ITEM 11. Amend rule 641—155.10(125,135) as follows:

641—155.10(125,135) Grounds for denial of initial license.

155.10(1) *Denial of application for licensure.* All programs applying for an initial license shall submit complete application information and shall be inspected by the department prior to the program's opening and offering services. A recommendation by the department of a denial of an initial application for licensure to the board committee may be made based on the following reasons:

a. to c. No change.

155.10(2) No change.

155.10(3) Board Committee action. The board committee shall meet to consider all cases involving issuance of a license. Upon approval of an application for licensure by the board committee, a license shall be issued by the department.

- a. Board Committee hearing preparation. The division will prepare all documents with a final recommendation for licensing determination to be presented at a board committee meeting within 120 days from the site visit. The division shall provide public notice of the date, time, and place of the meeting and the names of applicants to be reviewed and processed.
- (1) The division shall provide notice to the program 30 days prior to the board committee meeting notifying the program director and program board chairperson of the time, place, and date the board committee will review and act upon the application for the program along with the results of the inspection.
- (2) The division shall provide to all board <u>committee</u> members the following information on each application to be processed at the next <u>board committee</u> meeting: reports of the on-site program licensure inspections, and a final recommendation for licensing.
 - b. Board Committee meeting format.
 - (1) to (3) No change.
- (4) After all concerned parties are heard, the board committee will make a decision as to whether the applicant should be finally approved or initially denied a license to operate a substance abuse treatment program.
 - ITEM 12. Amend rule 641—155.11(125,135) as follows:

641—155.11(125,135) Suspension, revocation, or refusal to renew a license.

155.11(1) The board committee may suspend or revoke a license or refuse to renew a license for any of the following reasons:

- a. to i. No change.
- *j.* Conduct or practices found by the board committee to be detrimental to the general health, safety, or welfare of a client/patient or member of the general community.
 - k. to q. No change.
- r: Violating an order of the board committee or violating the terms or conditions of a consent agreement or informal settlement between a program and the board committee.
- 155.11(2) Initial notice from board committee. When the board committee determines to deny a renewal, suspend or revoke a license, the board committee shall notify the licensee by certified mail, return receipt requested, of the board's committee's intent to suspend, revoke, or refuse to renew the license and the changes that must be made in the licensee's operation to avoid such action. The initial notice shall further provide the licensee the opportunity to submit either a written plan of corrections or written objections to the department within 20 days from the receipt of notice from the board committee.
 - 155.11(3) Correction of issues or objections.
- a. Written plan of corrections. If a licensee submits a written plan of corrections, the licensee shall have 60 days from the date of submission within which to show compliance with the plan of corrections. The licensee shall submit any information to the board committee that the licensee deems pertinent to show compliance with the plan of corrections.
- b. Objections. If a licensee submits written objections, the licensee shall submit to the board committee any information that the licensee deems pertinent which supports the licensee's defense.
- **155.11(4)** Decision of board committee. Following receipt of a written plan of corrections and expiration of the 60-day time period, or following receipt of written objections, or when objections or notice of corrections have not been received within the 20-day time period, the board committee may meet to determine whether to proceed with the disciplinary action. The licensee shall receive notice of this meeting in the same manner as provided by 155.8(1) "a."
 - **155.11(5)** Notice of decision and opportunity for contested case hearing.
- a. When the board committee determines to suspend, revoke or not renew a license, the licensee shall be given written notice by restricted certified mail.
- b. The licensee may request a hearing on the determination. The request must be in writing and mailed to the department address within 30 days of the notice issued by the board committee. The request shall be sent by certified mail, return receipt requested. Failure to request a hearing will result in final action by the board committee.

155.11(6) Summary suspension. If the board <u>committee</u> finds that the health, safety or welfare of the public is endangered by continued operation of a treatment program, summary suspension of a license may be ordered pending proceedings for revocation or other actions. These proceedings shall be promptly instituted and determined.

ITEM 13. Amend rule 641—155.15(125,135) as follows:

641—155.15(125,135) Reissuance or reinstatement. After suspension, revocation or refusal to renew a license, the affected licensee shall not have the license reissued or reinstated within one year of the effective date of the suspension, revocation or expiration upon refusal to renew, unless by order of the board committee. After that time, proof of compliance with the licensure standards must be presented to the board committee prior to reinstatement or reissuance of a license.

ITEM 14. Amend rule 641—155.16(125,135) as follows:

641—155.16(125,135) Complaints and investigations.

155.16(1) Complaints. Any person may file a complaint with the department against any program licensed pursuant to this chapter. The complaint shall be made in writing and shall be mailed or delivered to the division director at the Division of Behavioral Health, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319-0075. A complaint form may be downloaded on-line at: http://www.idph.state.ia.us/bh/common/pdf/substance_abuse/complaint_form.pdf. The complaint shall include the name and address of the complainant, the name of the program, and a concise statement of the allegations against the program, including the specific alleged violations of Iowa Code chapter 125 or this chapter, if known. A complaint may also be initiated upon the board's committee's own motion pursuant to evidence received by the department. Timely filing of complaints is required in order to ensure the availability of witnesses and to avoid initiation of an investigation under conditions which may have been significantly altered during the period of delay.

155.16(2) No change.

155.16(3) *Investigative report.* Within 30 working days after completion of the investigation, the department shall prepare a written investigative report and shall submit the report to the executive director of the program, the chairperson of the governing body, and the board committee. This report shall include the nature of the complaint and shall indicate if the complaint allegations were substantiated, unsubstantiated, or undetermined, the basis for the finding, the specific statutes or rules at issue, a response from the program, if received, and a recommendation for action.

155.16(4) *Review of investigations.* The board committee shall review the investigative report at its next regularly scheduled meeting and shall determine appropriate action.

- a. Closure. If the board committee determines that the allegations contained in the complaint are unsubstantiated, the board committee shall close the case and shall promptly notify the complainant and the program by letter.
- b. Referral for further investigation. If the board committee determines that the case warrants further investigation, it shall refer the case to the department for further investigation.
- c. Written plan of corrective action. If the board committee determines that the allegations contained in the complaint are substantiated and corrective action is warranted, the board committee may require the program to submit and comply with a written plan of corrective action. A program shall submit a written plan of corrective action to the department within 20 working days after receiving a request for such plan. The written plan of corrective action shall include a plan for correcting violations as required by the board committee and a time frame within which such plan shall be implemented. The plan is subject to department approval. Requiring a written plan of corrective action is not formal disciplinary action. Failure to submit or comply with a written plan of corrective action may result in formal disciplinary action against the program.
- d. Disciplinary action. If the board committee determines that the allegations contained in the complaint are substantiated and disciplinary action is warranted, the board committee may proceed with such action in accordance with rule 641—155.11(125).

155.16(5) No change.

ITEM 15. Amend rule 641—155.18(125,135) as follows:

- **641—155.18(125,135) Deemed status.** The <u>board committee</u> shall grant deemed status to programs accredited either by a recognized national or not-for-profit accreditation body when the <u>board committee</u> determines that the accreditation is for the same services. Problem gambling treatment components shall not be granted deemed status under this rule, unless specifically reviewed by the accreditation body.
- **155.18(1)** National accreditation bodies. The national accreditation bodies currently recognized as meeting board committee criteria for possible deemed status are:
 - a. to d. No change.

155.18(2) Credentials and expectations of accreditation bodies.

- a. No change.
- b. Deemed status means that the board <u>committee</u> and division shall recognize, in lieu of their own review, an outside body's review, assessment, and accreditation of a hospital-based or freestanding community-based treatment program's operations, functioning, and services that correspond to those described in this chapter.

155.18(3) Responsibilities of programs granted deemed status.

- a. to d. No change.
- *e*. A program shall be currently accredited by a board committee-approved national accreditation body for services that are outlined in this chapter.

f. to h. No change.

155.18(4) The board committee and division shall retain the following responsibilities and rights when deemed status is granted to program/organizations:

- a. and b. No change.
- c. The board <u>committee</u> shall review and act upon deemed status if necessary when complaints have been founded, when national accreditation bodies find instances of noncompliance with accreditation, when the accreditation status of the program expires without renewal, when the program's accreditation status is downgraded or withdrawn by the accreditation body, or when focused reviews find instances of noncompliance.

155.18(5) No change.

ITEM 16. Amend rule 641—155.20(125,135) as follows:

641—155.20(125,135) Inspection. Each applicant or licensee agrees as a condition of licensure:

155.20(1) No change.

155.20(2) To permit properly designated representatives of the department to audit and collect statistical data from all records maintained by the licensee. A facility shall not be licensed which does not permit inspection by the department or examination of all records, including financial records, methods of administration, general and special dietary programs, the disbursement of drugs and methods of supply, and any other records the board committee deems relevant to the establishment of such a system.

- ITEM 17. Amend subrule 155.35(2) as follows:
- **155.35(2)** Required approvals. All opioid treatment programs shall be licensed or approved by the board committee and shall maintain all other approvals required by the Drug Enforcement Administration, Substance Abuse and Mental Health Services Administration and the Iowa board of pharmacy examiners in order to provide services.
 - ITEM 18. Amend subrule 155.35(17) as follows:
- **155.35(17)** *Deemed status.* The board committee shall grant deemed status to programs accredited either by a recognized national or not-for-profit accreditation body when the board committee determines that the accreditation is for the same services.
- a. National accreditation bodies. The national accreditation bodies currently recognized as meeting board committee criteria for possible deemed status are:

- (1) to (4) No change.
- b. Credentials and expectations of accreditation bodies.
- (1) The accreditation credentials of the bodies shall specify the types of organizations, programs, and services the bodies accredit and targeted population groups, if appropriate.
- (2) Deemed status means that the board <u>committee</u> and division shall recognize, in lieu of their own review, an outside body's review, assessment and accreditation of a hospital-based or freestanding community-based substance abuse program's operations, functioning, and services that correspond to those described in this chapter.
 - c. Responsibilities of programs granted deemed status.
 - (1) to (4) No change.
- (5) The program shall be currently accredited by a board <u>committee</u>-approved national accreditation body for services that are outlined in this chapter.
 - (6) to (8) No change.
- d. The board committee and division shall retain the following responsibilities and rights when deemed status is granted to program/organizations:
 - (1) and (2) No change.
- (3) The board <u>committee</u> shall review and act upon deemed status if necessary when complaints have been founded, when national accreditation bodies find instances of noncompliance with accreditation, when the accreditation status of the program expires without renewal, when the program's accreditation status is downgraded or withdrawn by the accreditation body, or when focused reviews find instances of noncompliance.
 - e. No change.
 - ITEM 19. Amend 641—Chapter 155, implementation sentence, as follows:

These rules are intended to implement Iowa Code sections 125.13₂ and 125.21 and 2009 Iowa Code Supplement section 135.150.